

<b>Title:</b>	<b>Standard Operating Procedures for Returned, Outdated, and Damaged Product</b>
<b>Issue Date:</b>	<b>5/2/2015</b>
<b>Effective Date:</b>	<b>1/8/2018</b>

## PURPOSE:

To ensure all personnel in the Safe Chain Solutions(SCS) Cambridge, MD warehouse are familiar with the procedure to be followed for handling returned, outdated, and damaged (ROD) prescription drugs as required by the most stringent law or regulation and in compliance with the

U.S. FDA reference number 21CFR§205.50.

## SCOPE:

All SCS warehouse personnel will know the correct actions to be taken and when to take those actions, (in accordance with the reference), with returned, outdated, and damaged prescription drugs.

## RESPONSIBILITIES:

<ul style="list-style-type: none"> <li>Logistics Coordinator</li> </ul>	<ul style="list-style-type: none"> <li>Visually inspect all products in Safe Chain inventory and returned to Safe Chain to ensure the product is suitable for re-entry into Safe Chain inventory.</li> </ul>
<ul style="list-style-type: none"> <li>Warehouse Supervisor</li> </ul>	<ul style="list-style-type: none"> <li>Visually inspect all products in Safe Chain inventory and returned to Safe Chain to ensure the product is suitable for re-entry into Safe Chain inventory.</li> </ul>
<ul style="list-style-type: none"> <li>Warehouse Manager</li> </ul>	<ul style="list-style-type: none"> <li>Ensure Logistics Coordinator and/or Warehouse Supervisor are properly trained in product inspection and handling.</li> <li>Visually inspect all products in Safe Chain inventory and returned to Safe Chain to ensure the product is suitable for re-entry into Safe Chain inventory.</li> </ul>

## GUIDELINES:

- If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container carton, or labeling, as a result of storage or shipping.
- The drug storage area contains a designated space for drug quarantine for outdated,

GOVERNMENT EXHIBIT  
604

1:24-cr-20255-WPD

damaged, deteriorated, misbranded or adulterated, counterfeit or suspected counterfeit drugs, and drugs that are in immediate or sealed, secondary containers that have been opened, that are awaiting disposition.

3. Written documentation of the disposition of outdated prescription drugs shall be maintained for three (3) years .
4. Customer's returns which were due to shipping mistakes i.e. wrong product, over shipment, etc. will be returned to stock/inventory upon passing product inspection. All return to stock returns must be returned in accordance with the manufacturer's recommended temperature ranges and all packaging and containers must be approved and double checked.
5. Quarantined products are not removed from the computerized inventory system until the product is destroyed or shipped back to the vendor or manufacturer.
6. All instructions given by the Board of Pharmacy and the Food and Drug Administration will be followed
7. No products are to be destroyed by employees of SCS. Waste Management Services, Inc provides these services.
8. All SCS personnel in the Cambridge warehouse will be trained to this Standard Operating Procedure.
  
1. RETURNS: The SCS client will inform their Designated Rep when there will be a return of product to our location.
  - a) The offices will then make arrangements with the client for the return of the product and document it.
  - b) A Return Merchandise Authorization (RMA) (see the attachment) will be completed by SCS client and SCS warehouse employee.
  - c) A copy of the pick slip will be attached to it.
  - d) Go onto the UPS computer, and send a return shipping label by email or print one and fax it to returner.
  - e) Fill out the RMA form, Shipping Use Only section. **NOTE:** Unless otherwise specified or the product is refrigerated, returns are always shipped back to SCS by UPS Ground.
  - f) File the form in the RMA file drawer.
  - g) When the product comes in, check the product for any damage. If the product being returned is noticed to be damaged immediately prior to signing for the package, it will be refused.
  - h) If the product is signed for and opened and discovered damage, contact a manager to make arrangements for the product to be returned to sender. The damaged product will be placed in quarantine until it is picked up or shipped.
  - i) Pull the corresponding RMA form; verify the product by checking the NDC, LOT, EXP and QTY and fill in the Date Return Received Section. If the product was returned do to a product recall, give the product and the RMA to the Logistics Manager and he will check the products against his records then put the product in quarantine awaiting disposition.
  - j) Give all other RMA's to the Logistics Manager and he will determine what should be done with the product.
  - k) All products being placed in quarantine for disposal shall be documented by updating the waste log folder in our SCS public drive.
2. DAMAGED, OUTDATED, AND COUNTERFEIT OR SUSPECTED COUNTERFEIT PRODUCTS:
  - a) If a product is noticed to be damaged immediately prior to signing for the package, it will be refused and sent back to the sender

Safe Chain

Solutions 822

Chesapeake Drive

Cambridge, MD

21613 If a products is signed for and opened and discovered damaged, this office will contact SCS management and they will contact the sender to make arrangements for the return to sender. The damaged product will be placed in quarantine until it is picked up or shipped.

- c) If a product is questionable, counterfeit or suspect, then this will be documented and reported to the Board of Pharmacy and the Food and Drug Administration (FDA) within three (3) business days and the drug will be held in quarantine area until the drug's disposition is authorized by the Board of Pharmacy and or the FDA.
- d) SCS starts treating a drug as outdated at six (6) months out from its expiration date. The product is placed in quarantine until it gets shipped out or disposed of. The products owner will be notified and SCS will handle accordingly.
- e) The waste log must be updated and the product will be disposed of through Waste Management Services, Inc.

<b>RETURN INFO</b>		<b>Pick List #</b>
<b>SCS Customer Name</b>	<b>Cust ID</b>	
<b>Date of Return Request</b>		
<b>Date of Original Order</b>		
<b>Reason for Return:</b>		
<b>Customer Contact</b>	<i>This section must be completed in full in order for return to be processed.</i>	
<b>Contact Name:</b>	<b>Contact Phone:</b>	<b>E-mail Address (for return shipping label):</b>
<b>Return Label Needed By:</b>		
<b>Purchasing Use Only:</b>		

Safe Chain

Solutions 822

Chesapeake Drive

NDC	Lot #	Qty	Exp
Cambridge, MD			
21613			

**Management Signature:** \_\_\_\_\_***Shipping Use Only:*****Date Return Label** \_\_\_\_\_**Shipping Notes** \_\_\_\_\_**Shipping Signature:** \_\_\_\_\_**Date Return Received:** \_\_\_\_\_**Lot #'s checked (please** \_\_\_\_\_**Qty confirmed (please** \_\_\_\_\_